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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/668,508	09/22/2000	Henry E. Young	1304-1-019CIP	1973

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EXAMINER

TON, THAIAN N

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/668,508

Applicant(s)

YOUNG ET AL.

Examiner

Thaian N. Ton

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25 July 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 14-17.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____

13. ☐ Other: _____.

For Walter
AUG 02

Continuation of 3. NOTE: The claims raise new issues of search and consideration with regard to the phrase "cells derived from all of the ectodermal and mesodermal lineages ...". The term "derived" would require a new search and/or consideration..

Continuation of 11. does NOT place the application in condition for allowance because: The prior rejection of claims 14-17, for written description, is maintained for reasons of record advanced in the prior Office actions. Applicants argue that the specification enables the skilled artisan to make and/or use the claimed invention and provides support for and describes the claimed invention, namely a pluripotent embryonic-like stem cells which is not a totipotent cells, and thereby does not give rise to functional gametes. Applicants point to the specification for the definition of totipotent cells, specifically that there is a distinction between totipotent cells and pluripotent cells; totipotent cells can form somatic cells from all three embryonic layers, as well as functional gametes, and pluripotent cells are capable of self-regeneration and differentiation to cells from all three embryonic layers. Applicants argue that the instantly claimed cells do not form gametes. The arguments of counsel cannot take place of evidence. There is no declaration or evidence of this claimed embodiment. Furthermore, there is no support in the specification with regard to pluripotent cells that do not give rise to functional gametes. The art recognizes that pluripotent cells can, for example in chimeric animals, give rise to functional gametes if they are incorporated into the germ line. Conversely, pluripotent cells which are not incorporated into the germ do not give rise to functional gametes. Thus, although totipotent cells clearly give rise to functional gametes, there is no support in the specification to show that the instantly claimed cells do not give rise to functional gametes. Accordingly, this rejection is maintained.

The prior rejections of claims 14-17, under 112, 2nd paragraph is maintained, as the claim amendments have not been entered.

The rejections of claims 14-17 under 35 USC §102 (b) as being anticipated by Povey et al. and Verma et al. are maintained for reasons of record advanced in the prior Office action. The rejection of claims 14-17 under 35 USC §103 (a) as being obvious over Pittenger in view of Sambrook is maintained for reasons of record advanced in the prior Office action. The proposed claim amendments are not entered, therefore the prior rejections apply. However, the recitation of "all" cells would obviate these rejections, as they only teach cells from one particular lineage.

The prior rejection of claims 14-16, as being anticipated by Capecchi is maintained for reasons of record. Applicants argue that pluripotent embryonic-like cells of the instant invention are not anticipated by Capecchi because they differ as a product, as well as being isolatable from a non-embryonic or post natal cell (i.e., made by a different process). Applicants agree that ES cells can and often do give rise to gametes, the point and distinction factually that totipotent cells, including ES cells give rise to gametes, whereas the pluripotent cells of Applicants cannot. The requirement to screen chimeric mice is as much a function and fact of the overall inefficiency of the process of genetic manipulation and generation of transgenic mice, as it is a reflection of the percentage, on a cell by cell basis, of totipotent ES cells which become gametes. These arguments are not persuasive. Pluripotent cells are encompassed by totipotent cells, that is, all totipotent cells are also pluripotent. Furthermore, the evidence that some ES cells do not give rise to functional gametes fulfill the limitations of the claims, as some of the cells, clearly, do not give rise to functional gametes. Applicants have not provided any evidence in the form of a declaration such that one of skill in the art could distinguish the claimed cells from cells as taught by Capecchi. Accordingly, this rejection is maintained.

The prior rejection of claims 14-16, as being anticipated by Piedrahita is maintained for reasons of record. Applicants argue, similarly, as above, that Piedrahita do not teach or anticipate the claimed cells because they teach the chimeric cells contributed to the germ line. Applicants point to p. 1321, introduction, which implies that germ line contribution was noted using PGCs, and thus, the PGCs, similarly to the arguments above, are totipotent, and can form gametes, and thus, cannot anticipate the claimed invention. As noted in the Abstract, some of the PGCs produced transgenic pigs, and one of the 20 fetuses analyzed had transgenic contribution. Piedrahita is directed to generation of chimeric pigs, in which germ line contribution can or cannot occur. The chimeric pig that resulted from this experiment did not appear to have germ line transmission. There is no indication that the pig was able to produce functional gametes, and Piedrahita teach that there was a weak positive signal in one testicle sample (see p. 1327, 1st column). Piedrahita teach PGCs, which contribute to chimera formation, and these cells have been shown not to produce functional gametes, as evidenced by the lack of germline transmission in the resultant animals.

The prior rejections of claims 14-17 under §103 (a) as being obvious over Shambloott in view of Sambrook, and Thomson in view of Sambrook are maintained for reasons of record. Applicants argue similarly with respect to each rejection, that Shambloott teach PGCs, and that these cells do not render the claimed invention obvious because the pluripotent cells taught by Shambloott are "capable of contributing to the germline" and forming gametes. This is not persuasive, as noted above. Pluripotent cells are encompassed by totipotent cells, and PGCs are considered pluripotent cells because they can, or cannot, contribute to germline transmission, as evidenced by Piedrahita (above). Applicants argue that Thomson do not render the invention obvious because they teach ES cells, which are totipotent cells, and can give rise to functional gametes. This is not persuasive. Thomson clearly states that their isolated cells are pluripotent. Thomson's cells fulfill the limitations of the claims, and the definition of the pluripotent cells, as defined by the specification. Accordingly, these rejections are maintained.